K103176

V.510(k) Summary

JAN 26 2011

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Date of Submission:	October 26, 2010
Submitter:	**DYMEDSO, Inc.**
Address:	**901A, Boul. Du Curé Boivin** **Boisbriand, Québec J7G 2S8** **CANADA**
Establishment Registration #:	**3004365906**
Contact:	**Yvon Robert, President**
Phone: **(450) 437-9601**	Fax: **(450) 437-2063**
Proprietary Device Name:	**Frequencer™ V2, Frequencer™ V2x**
Common Name of Device:	**Airway Clearance Device**
Classification Name:	**Percussor, Powered-Electric**
Device Class:	**2**
Product Code:	**BYI**

Predicate Device:
K100749 - **Frequencer™ v2x**

Description:
The **Frequencer™ V2** or **V2x** provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. It induces oscillatory sound waves in the chest by means of an electro-acoustical power head (hereafter referred to as the "transducer") which is placed externally on the patient's chest. The transducer is connected to a frequency generator which is capable of producing frequencies between 20 and 65 Hz. The transducer induces sound waves in the patient's chest which are effective in loosening mucus deposits. The model V2x uses disposable adapters with filters and is intended for use in multi-patient settings. The model V2 uses a permanent non-filtering adapter and is intended for single patient use.

Indications for Use:
The **Frequencer™ V2** or **V2x** provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. This device is intended to be a component of chest physiotherapy by providing a convenient method of external thorax manipulation.

It is indicated for patients having respiratory ailments which involve defective mucociliary clearance, as is typical in patients suffering from cystic fibrosis as well as chronic bronchitis, bronchiectasis, ciliary dyskinesia syndromes, asthma, muscular dystrophy, neuromuscular degenerative disorders, post-operative atelectasis and thoracic wall defects. Indications for this form of therapy are described in the Clinical Practice Guidelines for Postural Drainage Therapy of the American Association for Respiratory Care (AARC) published in 1991. This particular device provides a gentler, less painful form of therapy than the traditional "clapping" method of postural drainage therapy, allowing it to be used on patients who cannot be treated by clapping.

Comparison of Technological Characteristics:
The **Frequencer™ V2** and **V2x** are identical to the predicate device in terms of indications for use, contra-indications, acoustic operating principle and basic electronics. The electromagnetic compatibility of the predicate device only allowed for use in hospitals or clinics as opposed to a home or residential environment. Ferrites have been added to allow the current device to be used in a home or residence. The polymer material used for the adapters has been shown to be sufficiently biocompatible to allow skin contact. The **Frequencer™ V2x** is identical to the predicate device in that it uses disposable adapters with filters, and is intended for multi-patient use. The **Frequencer™ V2** comes with permanent non-filtering adapters and is intended for single patient use. Both adapter types are available in the same sizes as for the predicate device, namely 1", 2", 3", and 4" diameter. A flexible hose is now offered which may be affixed to the smallest adapter (1"), if deemed necessary, to accommodate situations where the weight of the transducer might cause discomfort.

Performance Testing
The device was tested in accordance with IEC 60601-1 for electrical safety and tested in accordance with IEC 60601-1-2 for electromagnetic radiation, with acceptance criteria consistent with a Type B device for domestic environments.

The base resin used in Bayblend 301 FR used for the adapter heads was tested in accordance with ISO 10993-5 and ISO 10993-10 "Biological Evaluation of Medical Devices" for cytotoxicity, sensitization and irritation, passing all tests. The adapter heads can therefore be considered Level 1 biocompatible and allow direct skin contact.

Performance bench testing was conducted to determine the maximum force applied by the device in comparison to the predicate device. The testing demonstrated a similar, though slightly lower maximum applied force in comparison to the predicate. Both devices still provide considerably lower forces than applied during Conventional Chest Physiotherapy (CCPT). The lower forces produced by the Frequencer™ may be able to provide a gentler

treatment compared to CCPT. Clinical testing conducted on the original Frequencer™ have demonstrated comparable sputum weights produced after treatment with the Frequencer™ in comparison to Conventional Chest Physiotherapy (CCPT) in subjects with Cystic Fibrosis (CF). In vitro flow rate measurements of mucus through a capillary tube also demonstrated higher flow rates of mucus when using the Frequencer compared to no treatment.

Conclusions:

The proposed **Frequencer™ V2** and **V2x** have the identical indications, operating principle and electronics as the predicate device **Frequencer™ v2x**. The only differences are the allowed environment, demonstration of biocompatibility of the polymer adapter, and availability of a model for home use with a permanent adapter. The performance testing provides validation of new features of this device. Thus, the proposed **Frequencer™ V2** and **V2x** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dymedso, Incorporated
C/O Ms. Jean Bigoney
Springfield Metallurgical Services, Incorporated
127 Main Street, PO Box 826
Springfield, Vermont 05156-0826

JAN 26 2011

Re: K103176
Trade/Device Name: Frequencer™ V2, Frequencer™ V2x
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: October 26, 2010
Received: October 28, 2010

Dear Ms. Bigoney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV.Indications for Use Statement

510(k) Number (if known):

Device Name: **Frequencer™ V2x, Frequencer™ V2**

Indications for Use:

The Frequencer™ V2x and Frequencer™ V2 provide airway clearance therapy and promote bronchial drainage by inducing vibration in the chest walls. This device is intended to be a component of chest physiotherapy by providing a convenient method of external thorax manipulation.

It is indicated for patients having respiratory ailments which involve defective mucociliary clearance, as is typical in patients suffering from cystic fibrosis as well as chronic bronchitis, bronchiectasis, ciliary dyskinesia syndromes, asthma, muscular dystrophy, neuromuscular degenerative disorders, post-operative atelectasis and thoracic wall defects. Indications for this form of therapy are described in the Clinical Practice Guidelines for Postural Drainage Therapy of the American Association for Respiratory Care (AARC) published in 1991. This particular device provides a gentler, less painful form of therapy than the traditional "clapping" method of postural drainage therapy, allowing it to be used on patients who cannot be treated by clapping.

Prescription Use__X_____ AND/OR Over-the Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number K103176